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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/552,011	10/07/2005	Harold Armando Gomez Torres	1556-0107PUS1	6281
2292 7590 12/21/2009 BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747				
EXAMINER				
WELTER, RACHAEL E				
ART UNIT		PAPER NUMBER		
1611				
NOTIFICATION DATE		DELIVERY MODE		
12/21/2009		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary**Application No.**

10/552,011

Applicant(s)GOMEZ TORRES, HAROLD
ARMANDO**Examiner**

RACHAEL E. WELTER

Art Unit

1611

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 June 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 2 and 4-20 is/are pending in the application.
- 4a) Of the above claim(s) 12 and 13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-2, 4-11, 14-20 is/are rejected.
- 7) ☒ Claim(s) 8 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Acknowledgment

Applicant is advised that the examiner assigned to this Application has changed. The examiner currently assigned to this application is **Rachael Welter**, whose contact information can be found at the end of the action.

Receipt of the amendment and remarks/arguments filed on 6/22/09 is acknowledged.

Claim Status

Claims 1-2 and 4-20 are pending. Claims 12-13 are withdrawn. Claims 1-2, 4-11, and 14-20 are drawn to the elected invention. Claim 3 is cancelled.

Specification

The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Withdrawn Rejections

The rejection of claims 1-3 rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 6190691 is withdrawn in light of applicant's persuasive arguments and a stronger rejection.

The rejection of claims 1-3, 7, 8 and 14 rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6190691 is withdrawn in light of applicant's persuasive arguments and a stronger rejection.

The rejection of claim 4 rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6190691 as applied to claims 1-3, 7, 8 and 14 above, and further in view of U.S. Patent 5446070 is withdrawn in light of applicant's persuasive arguments and a stronger rejection.

The rejection of claims 5 and 15-17 rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6190691 as applied to claims 1-3, 7, 8 and 14 above, and further in view of U.S. Patent 5051263 is withdrawn in light of applicant's persuasive arguments and a stronger rejection.

The rejection of claims 6 and 18-20 rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6190691 as applied to claims 1-3, 7, 8 and 14 above, and further in view of U.S. Patent 5024838 is withdrawn in light of applicant's persuasive arguments and a stronger rejection.

The rejection of claim 9 rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6190691 as applied to claims 1-3, 7, 8 and 14 above, and further in view of U.S. Patent 4276430 is withdrawn in light of applicant's persuasive arguments and a stronger rejection.

The rejection of claim 10 rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6190691 as applied to claims 1-3, 7, 8 and 14 above, and further in

view of U.S. Patent 544076 is withdrawn in light of applicant's persuasive arguments and a stronger rejection.

The rejection of claim 11 rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6190691 as applied to claims 1-3, 7, 8 and 14 above, and further in view of U.S. patent 6121254 is withdrawn in light of applicant's persuasive arguments and a stronger rejection.

Applicant's arguments with respect to the non-final rejection mailed 3/20/09 have been considered but are moot in view of the new ground(s) of rejection below.

Claim Objections

Claim 8 is objected to because of the following informalities. Applicant misspelled barrier. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1-2, 4-11, and 14-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites "...comprising carboxypolymethylene (carbopol) as a first thickening agent and an emulsifier agent in an aqueous carrier;..."

First, it is unclear from the limitation whether carbopol, which is in parentheses, is a required limitation. Additionally, it is noted that carbopol is a registered trademark. When a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe certain thickening agents and, accordingly, the identification/description is indefinite.

Second, it is unclear from the limitation whether carboxypolymethylene is a thickening agent and an emulsifier agent. Not until dependent claim 9 is it clear that the emulsifier agent is not carboxypolymethylene but triethanolamine. However, claim 1 is unclear and thus, appropriate correction is required.

Finally, it is unclear whether claim 1 is reciting components of a kit or whether the claim is drawn to a composition. In the instant specification according to example 1, the examiner notes that a carbopol gel is made, a carboxymethylcellulose gel is made, and then the two gels are combined with papain to make a single composition. In instant

claim 1, applicant is claiming a composition in the preamble but then claiming the gels separately. Thus, it seems as if applicant is claiming components of a kit.

For purposes of examination, the examiner will interpret the claim as a single composition comprising carboxypolymethylene, another thickening agent, a preservative, water, an active principle having proteolytic activity, and an anesthetic agent.

Moreover, dependent claim 14 is indefinite because it is unclear whether applicant wants an additional anesthetic agent to the one already recited in instant claim 1. If it was not applicant's intention to claim an additional anesthetic agent, the examiner notes that the claim fails to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-2, 4-10, and 14-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Klein (US Patent No. 5,980,918) in view of Parrilla (US Patent No. 5,024,838) and Beitner (US Patent No. 4,777,171).

Klein teaches a topical composition for healing treatment of burns that comprises 80-98 wt.% water, cereal-derived β -D-glucan, 0.1-5 wt.% triethanolamine, 0.01-2 wt.% carboxymethylcellulose, polyvinyl alcohol, 0.01-2.0 wt.% Carbopol carbomer, EDTA, and 0.01-2 wt.% paraben(s). According to Klein, parabens that can be incorporated in the composition include methylparaben, propylparaben, ethylparaben, butyl paraben, or mixtures thereof (column 4, lines 49-51). The composition may be formulated in various forms with creams and gels being preferred for application to the skin (abstract).

Klein does not teach the incorporation of an anesthetic agent or an active principle having proteolytic activity to its composition.

Parilla teaches a composition for the treatment of skin injuries, such as burns. According to Parilla, the composition can comprise a proteolytic enzyme, papain (claim 2). Parilla teaches that the enzyme in the composition reinforces proteolysis and speeds up the procedure of biochemical debridement (column 4, lines 6-8). Additionally, Parilla teaches that infections are avoided when using this composition and the time for cicatrization is shorter (column 4, lines 8-11). Parilla teaches that papain can be added in an amount of 0.005-0.5 wt.% (claim 1).

Beitner teaches a composition for the prophylactic and therapeutic treatment of trauma to the skin, particularly burns, sunburn, and frostbite (abstract). According to Beitner, a suitable local anesthetic can be incorporated in the topical preparation to provide immediate relief from burn pain. These local anesthetics include lidocaine hydrochloride in an amount of 0.1-10 wt.% (column 3, lines 37-47).

Therefore, it would have been obvious to an artisan of ordinary skill at the time the invention was made to add a proteolytic enzyme, such as papain to the topical composition of Klein. One would have been motivated to do so since the composition of Klein is used for treating burns and Parilla teaches that papain speeds up the procedure of biochemical debridement. Thus, one would have been motivated to add papain to the composition of Klein in order to reduce infections and shorten the time for cicatrization. Additionally, it would have been obvious to an artisan of ordinary skill at the time the invention was made to add an anesthetic agent, such as lidocaine to the composition of Klein. One would have been motivated to do so in order to provide immediate relief from burn pain, as suggested in Beitner.

Regarding the limitations directed to the amount of the instant components (i.e. carbopol, carboxymethylcellulose) in each gel and the amount of each gel in the composition (claims 7-8), the examiner directs applicant's attention to the 112, second paragraph rejection above. Since the examiner is interpreting the instant claims as being directed to a single composition (i.e. not a kit) and the examiner does not have access to laboratory equipment, burden is on applicant to prove that the amounts of the components in the prior art do not read on those instantly claimed. When the reference discloses all the limitations of a claim except a property or function and the examiner cannot determine whether or not the reference inherently possesses properties which anticipate or render obvious the claimed invention, the examiner can shift the burden of proof to applicant as in *In re Fitzgerald*, 619 F.2d 67, 205 USPQ 594 (CCPA 1980).

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Klein (US Patent No. 5,980,918) in view of Parrilla (US Patent No. 5,024,838) and Beitner (US Patent No. 4,777,171) as applied to claims 1-2, 4-10, and 14-20 above and in further view of Chen (US Publication No. 2003/01700182).

The disclosures of Klein, Parrilla, and Beitner are described above.

Klein, Parrilla, and Beitner do not teach the addition of chlorhexidine and/or urea to its compositions.

Chen teaches a topical spray for burn treatment (abstract) that incorporates chlorhexidine that can be incorporated in an amount of 0.05-10 wt.% of a cream, lotion, or gel (paragraph 0021, 0022). According to Chen, chlorhexidine is an antiseptic and disinfectant effective against a wide range of bacteria, some fungi, and some viruses (paragraph 0021).

Therefore, it would have been obvious to an artisan of ordinary skill at the time the invention was made to add chlorhexidine to the composition of Klein used for the treatment of burns. One would have been motivated to do so in order to prevent infection from bacteria, fungi, and some viruses in a burn wound, as suggested in Chen.

Conclusion

Claims 1-2, 4-11, and 14-20 are rejected. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to RACHAEL E. WELTER whose telephone number is (571) 270-5237. The examiner can normally be reached 7:30-5:00 Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached at 571-272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

REW

/Lakshmi S Channavajjala/

Primary Examiner, Art Unit 1611

December 15, 2009